DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 1, 2014

AmeriWater, Inc.
Mr. Brian R. Bowman
Quality & Regulatory Administrator
1303 Stanley Avenue
Dayton, OH 45404

Re: K142285
Trade/Device Name: AmeriWater Heatsan
Regulation Number: 21 CFR 876.5665
Regulation Name: Water Purification System for Hemodialysis
Regulatory Class: II
Product Code: FIP
Dated: October 29, 2014
Received: October 31, 2014

Dear Mr. Bowman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

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Enclosure

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Indications for Use

510(k) Number (if known): K142285

Device Name: AmeriWater Heatsan

Indications For Use:

The AmeriWater Heatsan is an optional accessory for water treatment systems intended for use in hemodialysis applications. The Heatsan is designed to heat water received from the water purification system, and circulate the heated water around the distribution loop at a controlled sanitizing temperature (minimum temperature of 185°F) for a programmed length of time (minimum hold time of 2 hours) to provide heat disinfection of the water distribution loop. The AmeriWater Heatsan is intended for use in hospitals, clinics, or dialysis centers to provide heat disinfection resulting in total viable microbial counts below 50 CFU/ml.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(K) SUMMARY

November 25, 2014

510(K) Number: **K142285**

Submitter: AmeriWater

Contact: Brian R. Bowman, Quality & Regulatory Administrator
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Proprietary Name: AmeriWater Heatsan

Common Name: Heat Sanitization System

Classification Name: Tank, Holding, Dialysis and Accessories

Classification: Class II Medical Device under §876.5665
Panel: Gastroenterology
Product Code: FIP

Equivalent Device: K093641, TANGO$_3$ Ozone System

Device Description: The AmeriWater Heatsan is intended for use in hospitals, clinics, or dialysis centers to provide heat disinfection resulting in total viable microbial counts below 50 CFU/ml. It is an integrated hot water disinfection unit that incorporates equipment to heat water received from a direct feed Water Purification System , and circulate around a distribution loop at a controlled sanitizing temperature (minimum temperature of 185°F) for a specified length of time (minimum hold time of 2 hours). The Heatsan system has been designed to be in compliance with the requirements of *ANSI/AAMI/ISO 13959:2009 Water for hemodialysis* and related therapies and *ANSI/AAMI/ISO 26722:2009 Water treatment equipment for hemodialysis applications and related therapies*. The operation of the Heatsan unit is controlled entirely through the touch screen panel located on the front of the main control box. The touch screen display panel displays systems performance data and the status of the device. The Heatsan unit incorporates monitoring devices and will report alarms and warnings messages via the user display. The Heatsan is used only during non-treatment hours when there are no patients being dialyzed. There is no patient contact with the device.

The unit can be configured to disinfect up to two distribution loops, either individually or together. The user can set for each day of the week which loop is to be disinfected and in what configuration. The Heatsan has been designed to provide up to 100 gallons of hot water for the purpose of sanitizing connected dialysis equipment. The number of machines that can be disinfected at any one time will be dependent on the requirement of those machines regarding the amount of water each machine needs for disinfection, the time taken to perform heat disinfection and the flow at which they require the hot water. When in “Dual” mode, sanitizing two distribution loops, the unit can potentially supply up to 200 gallons of water so that 100 gallons of water will be available for each distribution loop. Following disinfection of the first loop the unit will refill and reheat to disinfection temperature then proceed automatically to disinfect the second distribution loop.

The system allows the user to input the specific requirements of the dialysis machines to be disinfected, the days requiring heat disinfection and the times which heat disinfection can occur. If the system detects that any of the entered user values cannot be achieved by the Heatsan unit the unit will raise an “Incorrect number” alarm warning the user that the parameters loaded cannot be achieved.

The Heatsan operation stages include Pre-heat, Heating, Hold, Water draw off, and Cool down. The typical stage duration times for disinfection are as follows: Pre-heat 120 minutes, Heating 120 minutes, Hold* 120 minutes, Water draw off 60 minutes, Cool down 60 minutes.

* To provide clarification the operation of the system during the "Hold" period, the water continues to circulate through the loop and the Heatsan system tank to maintain the water temperature. The word "hold" refers to the action of the Heatsan holding, or maintaining, the sanitize temperature during the programmed hold time.

The pre-heat stage is initiated prior to Heatsan start time. The start and return to service times are set by the clinical staff. During the preheat stage the unit fills the tank with only the amount of permeate needed for the number of machines programmed in by the operator. This feature saves both power and water consumption. The heaters then raise the temperature to 122^{o}F and hold it until the timed Heatsan start period is reached. The pre-heat stage reduces the risk of thermal shock to pipe work and reduces the time taken to achieve disinfection temperature.

Once the pre-programmed "start Heatsan" start time has been reached the Heatsan will either directly or indirectly isolate the RO plant from the distribution loop. The Heatsan will then be manually or automatically connected to the distribution loop using the manual or motorized valves on the associated manifold. The internal pump will then start to circulate the preheated water around the distribution loop(s) to be disinfected. The system will continue to pre-heat the water until the preset disinfection temperature is achieved. The default circulation period is set for 120 minutes. After the "Circulation" stage has timed out the system is then held at disinfection temperature for a minimum of 120 minutes. The temperature is maintained by the switching on of only one of the heaters to save power.

After successful hold period the unit will signal that water is available for disinfection. The minimum default time for this stage is set at 60 minutes. The maximum time is calculated from the times pre-programmed in by the user relating to the stop/start times and the duration for the heat disinfection cycle on the connected dialysis machines. For example if the heat disinfection cycle time for a particular dialysis machine is 40 minutes at 39 minutes from the end of timed water draw off period the system will signal that there is insufficient time to run any further machine cycles. When the system detects that the volume of water has fallen below the minimum required to disinfect a single dialysis machine the unit will signal, flashing the Heatsan indicator lamp.

Once the water availability stage has timed out the system will proceed into automatic "Cool down". The system will perform a series of tank drain downs and introduce cold RO permeate into the distribution loops until the return temperature on the system falls below 86^{o}F. On reaching this temperature the system automatically disconnects itself from the distribution loop and re-introduces the RO units. Following the Cool down period the tank drain valve will remain open until the tank level falls to zero at which point the unit will return to **"Standby".** To ensure that the tank remains empty during "standby" the drain valve will open for 5 minutes every 2 hours.

Indications for Use: The AmeriWater Heatsan is an optional accessory for water treatment systems intended for use in hemodialysis applications. The Heatsan is designed to heat water received from the water purification system, and circulate the heated water around the distribution loop at a controlled sanitizing temperature (minimum temperature of 185°F) for a programmed length of time (minimum hold time of 2 hours) to provide heat disinfection of the water distribution loop. The AmeriWater Heatsan is intended for use in hospitals, clinics, or dialysis centers to provide heat disinfection resulting in total viable microbial counts below 50 CFU/ml.

Statement of Substantial Equivalence: The AmeriWater Heatsan is substantially equivalent to the TANGO$_3$ Ozone Disinfection System (K093641). The system design presents no new issues of safety or effectiveness. The following table compares and contrasts the predicate device and the new device. This table along with the documentation included in this submission demonstrates that there are no new issues of safety or effectiveness associated with this device, and that the device is substantially equivalent to the predicate device. Results of performance testing indicate that the device is as safe and effective for its intended purpose and performs as well or better than the predicate device when used in accordance with the instructions for use.

PREDICATE DEVICE COMPARISON TABLE	Predicate Device $TANGO_3$ Ozone System (K093641)	AmeriWater Heatsan
Indications for Use	The $TANGO_3$ Water Storage Tank with Ozone Disinfection System is intended to be used for disinfection of the water distribution system of a dialysis facility. The tank of the $TANGO_3$ is also used as the water holding tank of the distribution system. The disinfection process is completely automated. Ozone concentration during disinfection is between 0.2 ppm and 0.3 ppm. The distribution system will be exposed to ozone for one (1) period of 45 minutes and three (3) subsequent periods of 30 minutes with adequate water flushes between them and at the end, leaving the distribution loop without ozone.	The AmeriWater Heatsan is an optional accessory for water treatment systems intended for use in hemodialysis applications. The Heatsan is designed to heat water received from the water purification system, and circulate the heated water around the distribution loop at a controlled sanitizing temperature for a programmed length of time to provide heat disinfection of the water distribution loop. The AmeriWater Heatsan is intended for use in hospitals, clinics, or dialysis centers to provide heat disinfection resulting in total viable microbial counts below 50 CFU/ml.
For Use In	Hospitals	Hospitals, clinics, or dialysis centers
Disinfection For	Water Distribution System	Water Distribution System
Power Requirements	208V-240V, 1-phae or 3-phase, 50/60Hz	208,460,575V; 60 Hz; 3-ph
Means of Disinfection	Ozone	Heated Water
Working Tank Volume	250 gallons	100 gallons
Disinfect Start	User or automatic start	User or automatic start
Operation	Automated	Automated
Process	• Tank filled with pure water, • Ozone introduced to water in tank, • Ozonated water circulated in loop, • Drain and refill tank and loop.	• Tank filled with pure water • Water in tank gradually heated • Water temperature maintained • Hot water circulated in loop • Cool down/flush (tank drain & refill with pure water until temperature drops below 86°F).
Water contacting materials	Stainless Steel, HDPE, Lexan, Acrylic, Teflon, Viton, Kynar, PVC	Polypropylene, Stainless Steel, Viton, Silicone, Nitrile, Ceramic, EPDM, Inconel 625

The AmeriWater Heatsan has the same operational characteristics as the heat disinfection portions of the Gambro Central Water Treatment System CWP 100 – WRO H cleared for market under K974899. The heat disinfection portion of the Gambro Central Water Treatment System CWP 100 – WRO H consists of a stainless steel tank and an electrical heater. The tank is filled with pure water from the WRO unit, and the heater gradually heats and maintains the temperature of the pure water in the tank at either 140°F (Low) or 194°F (High). Likewise, the AmeriWater Heatsan consists of a stainless steel tank and electrical heaters. The tank is filled with pure water from the water purification system, and the heaters gradually heat and maintain the temperature of the pure water in the tank at a programmed temperature between 185 – 203°F. Both systems use a circulation pump to circulate the hot water in the pure water distribution loop. During the disinfection process, both systems are capable of integrated heat disinfection with the dialysis machines if the dialysis machines have a heat disinfection capability. In both systems, the tank is automatically refilled with pure water during different stage of the process.

Summary of Performance Testing: Non-clinical testing was conducted to verify and validate the efficacy of the system in the reduction of bacteria in a water distribution system. Dialysate delivery systems and water purification systems for hemodialysis are not considered critical or semi-critical devices by FDA and therefore do not require sterilization or high-level disinfection. The objective of the heat disinfection study was to validate the heat disinfection process following an inoculation procedure. The testing simulated as closely as possible the worst-case conditions under which a heat disinfection system is used. Testing was conducted with

clinically relevant waterborne organisms. The organisms used were wild type waterborne microorganisms that have been implicated in disease outbreaks in dialysis clinics. Burkholderia cepacia and Mycobacterium abscessus were the organisms used in the study. A total of three test runs were conducted with each organism. The study was intended to demonstrate that hot water will achieve a minimum of a 6-log reduction of Burkholderia cepacia and a minimum of a 3-log reduction of Mycobacterium abscessus as required by FDA for intermediate-level disinfection. The results of microbiological testing show evidence that the device is effective in the reduction of bacteria in the water distribution system.

Biocompatibility: There are no direct or indirect patient-contacting components in this device. There is no contact between the patient and any part of the device nor is the device invasive. The Heatsan is used for disinfection of the direct feed distribution loop during non-treatment hours. This device will never be used during patient treatment and there is no direct or indirect patient contact. The water contacting materials are the same as other water treatment devices produced by AmeriWater (K924695, K991519, K111740, and K051031). The water contacting materials are as follows: 316 stainless steel, silicone, ceramic, Inconel 625, Nitrile, Viton (FKM), EPDM, and polypropylene. Leachable testing was conducted to determine if exposure of the components of the AmeriWater Heatsan Disinfection system in conjunction with a direct feed water loop (as used in the AmeriWater Water Purification System) to heated water results in leaching, and to demonstrate the absence of toxic leachables. The test was designed to expose the Heatsan Disinfection System in conjunction with the direct feed loop, to heated water when operating the system per the instructions for use for the device. Testing for conductivity was conducted in accordance with USP 35 / NF 30 <645> requirements, and testing for total organic carbon (TOC) was conducted in accordance with USP 35 / NF 30 <643> requirements. Results of testing indicated that there was no increase in water conductivity, and the TOC level remained below 500 ppb for both test runs indicating that exposure of the components of the AmeriWater Heatsan Disinfection system in conjunction with a direct feed water loop (as used in the AmeriWater Water Purification System) to heated water does not result in leaching, and demonstrated the absence of toxic leachables.

Electrical Safety: The AmeriWater Heatsan device is intended for use in water rooms in a dialysis clinic or hospital, and is not used in the patient treatment area. There is no direct contact between the patient and any part of the device nor is the device invasive. The device is intended for use only during non-treatment hours. Therefore, the device was tested to IEC 61010 standards. Intertek completed the testing, and provided an ETL listing report for the device. Results of testing indicate that the device complies with all electrical safety requirements of the standard. End of line electrical safety testing is conducted on 100 percent of produced Heatsan products as required by the ETL listing for the device.

Software: The water purification system for hemodialysis (WPS) is as device with a moderate level of concern, and the Heatsan is an accessory used to sanitize the distribution portion of the WPS device. Therefore, the Heatsan device is considered a moderate level of concern. Software validation for the Heatsan software was conducted in accordance with FDA guidance for software with a moderate level of concern. The results of validation indicate that the software performs as intended.

Test results from performance testing, biocompatibility testing, software validation, and electrical safety testing indicate that the device is as safe and effective for its intended purpose as the predicate device.